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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,236	07/12/2004	Thomas Beckert	253871US0PCT	3554

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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER
SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
07/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/501,236	BECKERT ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *9 and 13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/12/04;10/4/04;5/12/05;9/16/05;3/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Applicant's election without traverse of Group I (claims 1-13) and election of species: 1a) claims 2-16; 2a) pellets in capsule and 3a) capsule in the reply filed on 04/28/08 is acknowledged. Examiner also acknowledges the Information Disclosure Statements (IDS) filed 07/12/04, 10/04/04, 05/12/05, 09/16/05 and 03/27/06.

Claim 9 and 13-16 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 28 April 2008.

Claims 1-16 are pending in this action. Claims 9 and 13-16 have been withdrawn (non-elected invention). Claims 1-8 and 10-12 are being examined in this action. Claims 1-8 and 10-12 are rejected.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the limitation "an inner layer, which may where appropriate be applied to a core" is unclear as to whether or not the inner layer is required to be applied to the core and if so, under what conditions should it be applied to the core. It appears that Applicant intended application of the inner layer to the core to be an optional feature. If this is the case, the claim should be amended to recite "an inner layer, optionally applied to a core...".

Claim 1 is indefinite based on the limitation of the "inner layer, with the active ingredient budesonide, bound in a binder". It is unclear as to whether the binder component and the budesonide are both provided in the same inner layer or whether the inner layer is composed of a multi-layered construction, whereby the budesonide is bound in one of the layers.

Claim 1 is also indefinite based on the limitation, "pharmaceutically usual excipients". More definitive language would be "pharmaceutically *acceptable* excipients".

Claim 8 recites the limitation "wherein the capsule" in line 2. There is insufficient antecedent basis for this limitation in the claim. (It appears claim 8 should be dependent upon claim 7, rather than claim 6).

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beckert *et al.* (hereinafter "Beckert") (WO 01/68058).

Beckert ('058) teaches a multilayer pharmaceutical product that substantially comprises a) a core containing a pharmaceutically active substance, b) an inner coating consisting of a copolymer or a mixture of copolymers that are composed of 85 to 98 wt.% of radically polymerized C_1 to C_4 alkyl esters of the acrylic or methacrylic acid and 15 to 2 wt.% of meth(acrylate) monomers with a quaternary ammonium group in the alkyl group, and c) an outer

coating consisting of a copolymer that is composed of 75 to 95 wt.% of radically polymerized C_1 to C_4 alkyl esters of the acrylic or methacrylic acid and 5 to 25 wt.% of meth(acrylate) monomers with an anionic group in the alkyl group. The product is used for producing a pharmaceutical product that releases the active substance contained therein according to the USP release test, at pH 1.2 during 2 hours and subsequent rebuffering to pH 7.0, by less than 5% after 2.0 hours after start of the test and by 30 to 80% % after eight hours after start of the test (Abstract). The active substance can be budesonide. The dosage form includes a binder such as collidon 25 as well as an internal coat of Eudragit RS and RL and an external enteric coating of Eudragit FS (Example 1 - pages 16-18).

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Beckert.

* * * * *

Claims 1-8 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ulmius (U.S. Pat. No. 5,643,602).

Ulmius ('602) teaches oral pharmaceutical compositions for use in the treatment of inflammatory bowel diseases comprising corticosteroids, such as budesonide (see column 1, lines 10-15); (col. 3, lines 9-15). The composition is formulated as a multiple unit composition in a capsule (col. 4, lines 50-50). Each unit comprises a core, a first layer on the core and a second layer on the first layer. The core consists of a non-pareil seed to which the glucocorticosteroid is applied or a seed in which the glucocorticosteroid is homogeneously distributed. Excipients used to prepare the seeds include polymeric binding agents (col. 5, lines

3-11). The first layer on the non-pareil seeds comprises the glucocorticosteroid and a water-soluble or water-insoluble polymer which acts both as a binder for the glucocorticosteroid and as a rate-limiting layer for release of the glucocorticosteroid. Preferred film-forming polymers taught include ethylcellulose or copolymers of acrylic and methacrylic acid esters such as EUDRAGIT® NE, EUDRAGIT® RL and EUDRAGIT® RS (col. 5, lines 12-26). Suitable polymers for the second layer are taught at column 5, lines 34-48.

The Examples demonstrate various embodiments of the invention. For instance, Example 1 at column 8 shows preparation of a budesonide formulation. Budesonide was suspended in Aquacoat ECD 30 dispersion with the aid of Polysorbate 80 together with acetyltributyl citrate. The mixture was sprayed onto sugar spheres in a fluid bed apparatus. The enteric coating consisted of, among other components, the Eudragit L100-55 dispersion, which was then sprayed on the spheres. The pellets were dried, sieved and filled into hard gelatin capsules.

The instant invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, given the teachings of Ulmius. Ulmius provides for a multi-layered constructed pharmaceutical formulation comprising the same active ingredient – budesonide, with the same polymeric components (*i.e.,* binder) and formulated for the same field of endeavor as that instantly desired by Applicant.

* * * * *

Information Disclosure Statement

Examiner kindly requests a certified English translation of Foreign document - WO 01/68058 (Beckert *et al.*) in reply to this Action.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1618

hns

June 23, 2008